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MERCHANT & GOULD PC			TREYGER, ILYA Y	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,687	Applicant(s) GORDON, ANGUS BUCHAN	
	Examiner ILYA Y. TREYGER	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 24 is/are pending in the application.
- 4a) Of the above claim(s) 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/23/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claim 24 is new.
2. Claims 1-22 and 24 are examined on the merits.

Response to Arguments

Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

- 3.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

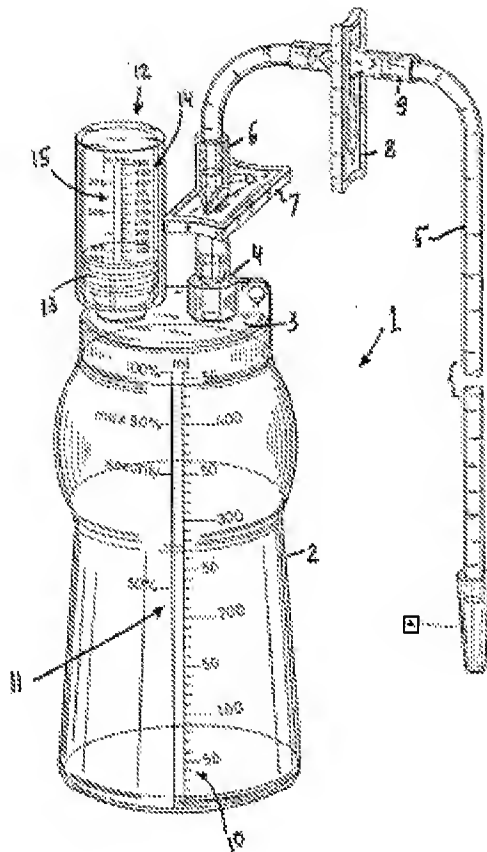
5. Claims 1-3, 6, 10, 22, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Harle (US 4,642,093).

6. In Re claims 1-3, Harle discloses an aspirator for withdrawal of secretions from wounds comprising:

a pre-evacuated chamber 2 (Abstract, line 2; Col. 3, line 56; Fig.) fully capable of being steril (claim 3);

a flexible hose 6 (Col. 3, line 62; Fig.), which is a drainage tube connecting the pre-evacuated chamber 2 to the tip A (Fig.), which is a variation of the needle; and

a clamp 7 (Col. 3, line 63; Fig.), which is a sliding clamp (claim 2).



7. In Re claim 6, Harle discloses the closed drainage device wherein the pre-evacuated chamber is cylindrical (See Fig.).
8. In Re claim 10, Harle discloses the closed drainage device wherein the pre-evacuated chamber is made of plastic (See Col. 3, ln. 57-58).
9. In Re claim 22, Harle discloses the closed drainage device wherein the drainage tube is fully capable to be connected to the pre-evacuated chamber at manufacture.
10. In Re claim 23, Harle discloses the method for removing fluid from a body cavity, which comprises inserting the free end portion 51, which is variation of needle into the body cavity (Col. 4, lines 19-22).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harle (US 4,642,093).

14. In Re claim 4, Harle discloses the invention discussed above, but does not expressly disclose the particular parameter of the pre-evacuated chamber pressure range.

The particular pressure range of the pre-evacuated chamber depends of the quantity of the liquid has to be drained what in its turn depends of the particular character of the wound or/and surgical procedure, and therefore is the matter of optimization. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the pre-evacuated chamber having the pressure range depending of the intended use of

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the device since discovering the optimum or workable ranges involves only routine skill in the art.

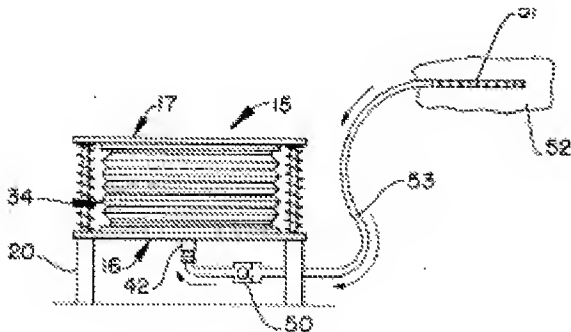
15. In Re claim 5, Harle discloses the invention discussed above, but do not expressly disclose the particular parameters of the pre-evacuated chamber volume.

The particular parameters of the pre-evacuated chamber volume depends of the quantity of the liquid has to be drained what in its turn depends of the particular character of the wound or/and surgical procedure, and therefore is the matter of optimization. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the pre-evacuated chamber having the volume depending of the intended use of the device since discovering an optimum value of a result effective variable involves only routine skill in the art.

16. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harle (US 4,642,093) in view of Lewis, Jr. (US 3,809,087).

17. In Re claim 7, Harle discloses the invention discussed above, but does not expressly disclose the apparatus, wherein the evacuated chamber is folded.

Lewis discloses the closed drainage device wherein the pre-evacuated chamber 34 is folded since bellows design is a foldable and corrugated (claim 9) design (See Fig.).



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It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Harle with the foldable design, as taught by Lewis in order to utilize the conventionally known design of the evacuated chamber.

18. In Re claim 8, Harle in view of Lewis disclose the invention discussed above but do not expressly disclose the pre-evacuated chamber folded into the form of a “catherine wheel”.

Since the criticality of folding the pre-evacuated chamber into the form of a pinwheel (catherine wheel) claimed by Applicant is not supported by any showing of criticality of form in the instant specification, nor did Applicant stated that such form serves any specific purpose or performs any specific function other than the function disclosed in Lewis, it would have been obvious to those skilled in the art at the time the invention was made to fold the pre-evacuated chamber into the form of a pinwheel as an obvious design choice, and as such it does not impact the patentability of claim 8.

19. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harle (US 4,642,093) in view of Gilcher et al. (US 4,385,630).

Harle discloses the invention discussed above but do not expressly disclose the device wherein the needle is a gauge needle, and particularly a 19 gauge needle.

Gilcher teaches the blood donation unit (blood drainage device) wherein the needle is a gauge needle and particularly the 19 gauge needle (Col. 4, ln. 13, 14).

All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of applying the 19 gauge needle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the

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system suggested by the cited prior art with the gauge needle, and particularly 19 gauge needle as disclosed by Gilcher in order to provide a system with the needle that is known in the art to be suitable for such purposes.

20. Claim 17 rejected under 35 U.S.C. 103(a) as being unpatentable over Harle (US 4,642,093) in view of Olaussen (US 6,113,568).

Harle discloses the invention discussed above but do not expressly disclose the device wherein the needle is a venflon needle.

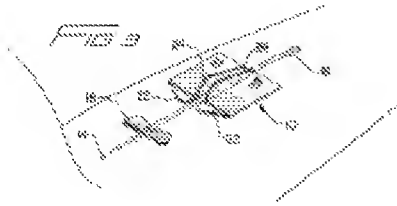
Olaussen teaches the vein catheter wherein the needle for draining body fluid is a venflon needle (See Col. 3, ln. 24-26).

All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of using the venflon needle for draining the body fluids. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the system suggested by the cited prior art with the venflon needle as disclosed by Olaussen in order to provide a system with the needle that is known in the art to be suitable for such purposes.

21. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harle (US 4,642,093) in view of Hogan (US 4,820,282).

Harle discloses the invention discussed above but do not expressly disclose the device wherein the needle is a butterfly needle.

Hogan teaches the use of butterfly needle 16 for draining the body fluids from the patient (See Fig. 3).

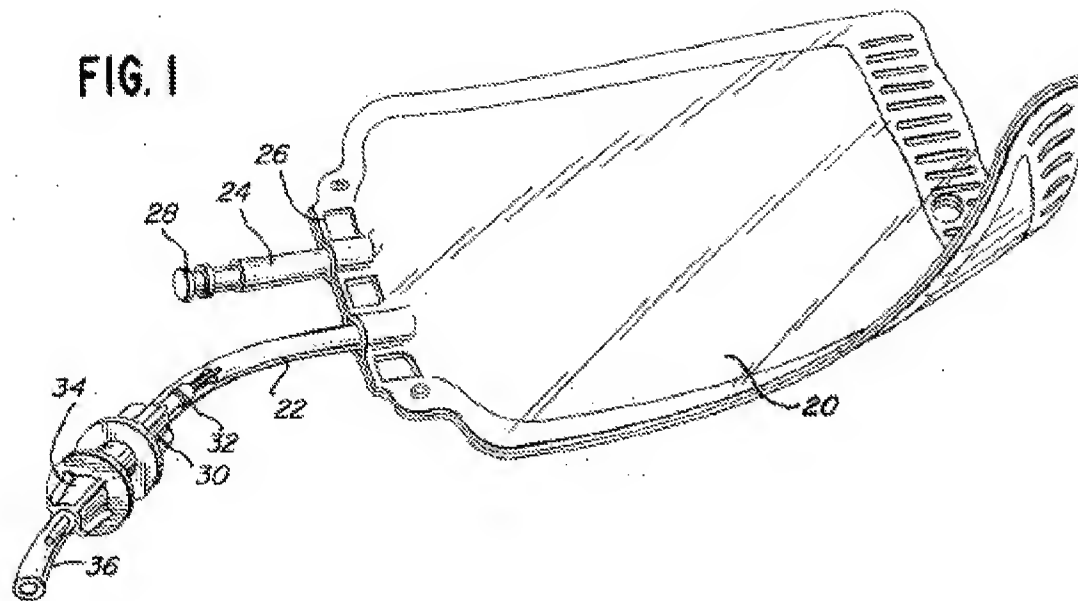


All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of the butterfly needle used for draining body fluid from the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the system suggested by the cited prior art with the butterfly needle as disclosed by Hogan in order to provide a system with the needle that is known in the art to be suitable for such purposes.

22. Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis, Jr. (US 3,809,087) in view of Dennehey (US 4,294,250).

Harle discloses the invention discussed above but do not expressly disclose the drainage apparatus wherein elements of the device are connected by a Luer-Lock mechanism.

Dennehey teaches the use of Luer-Lock connection device 34 for coupling elements of apparatus fully capable of performing drainage function (See Abstract, ln. 1-13: Fig. 1).



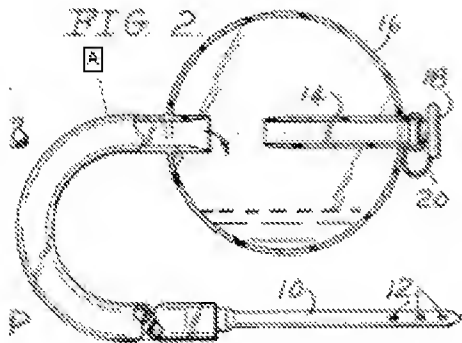
All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of coupling drainage device elements by Luer-Lock mechanism. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the system suggested by the cited prior art with the coupling mechanism as disclosed by Dennehey in order to provide a system with the Luer-Lock device that is known in the art to be suitable for such purposes.

23. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friend (US 3,982,546) in view of Broadnax, Jr. (US 5,067,950).

Friend discloses the device for draining a body cavity comprising:

a flexible reservoir 16 (pre-evacuated chamber); and

a drainage tube A connecting the pre-evacuated chamber 16 to a needle 10, wherein the vacuum port 14 has a plug 18 (See Col. 4, ln. 13, 14; Fig. 2).



Friend does not expressly disclose the drainage device comprising the clamp attached to the connection tube, wherein the clamp has opened and closed position.

Broadnax teaches the wound drainage device wherein the tube is provided with the sliding clamp 14 (Fig. 1) having closed and opened positions.

The rationale of obviousness rejection discussed above in claim 1 is incorporated herein in its entirety.

24. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over TRACE (US 2,936,757) in view of Broadnax, Jr. (US 5,067,950).

TRACE discloses the surgical drainage apparatus comprising:

a pre-evacuated chamber 10 (Fig. 1);

a drainage tube 31 (Fig. 1) connecting the pre-evacuated chamber 10 to a needle (See Col. 2, ln. 32-36), wherein the vacuum port 14 has a plug 18 (See Col. 4, ln. 13, 14; Fig. 2); and

a the tube (access port) 80 (Fig. 6) fully capable of enabling the retrieval of a samples of fluid from the chamber and of comprising the tap.

TRACE does not expressly disclose the drainage device comprising the clamp attached to the connection tube, wherein the clamp has opened and closed position.

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Broadnax teaches the wound drainage device wherein the tube is provided with the sliding clamp 14 (Fig. 1) having closed and opened positions.

The rationale of obviousness rejection discussed above in claim 1 is incorporated herein in its entirety.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilya Y Treyger/
Examiner, Art Unit 3761

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